II. REMARKS

Upon entry of this Amendment, claims 2 and 7 to 27 will be pending. Claim 2 is amended. Support for the foregoing amendment can be found throughout the specification and claims as originally filed. No new matter is added by way of this amendment.

The Applicants thank the Examiner for the withdrawal of the rejection of 35 U.S.C. § 112, second paragraph.

1. Claim Rejections under 35 U.S.C. § 101:

Claims 2 and 7 to 27 were rejected under 35 U.S.C. § 101, because the claimed invention allegedly "lacks patentable utility." Office Action at page 2. The Applicants respectfully traverse this rejection.

Functions for the claimed nucleic acid molecules are set forth in the specification as filed including encoding triose phosphate isomerase, vacuolar H^+ translocating-pyrophosphatase, sucrose synthase, hexokinase, fructose 1,6-bisphosphate aldolase, fructose 6-phosphate 2-kinase, invertase, fructokinase, NDP-kinase, or UDP-glucose pyrophosphorylase. Specification at page 24, lines 7-14. In addition, the specification describes multiple other utilities including isolating a variety of agronomically significant genes, acquiring molecular markers, promoters, cis-regulatory elements, identifying polymorphisms, and as probes for assisting in the isolation of full-length cDNAs or genes, gene mapping, isolation of homologous sequences, and the detection of gene expression. *See, e.g.*, specification at page 82, line 18 *et seq*, under the heading "Uses of the Agents of the Invention."

The Examiner does not consider any of these disclosed utilities as persuasive because the specification apparently does not disclose utilities "specific to the claimed nucleic acids and are generally applicable to any nucleic acid." Office Action at page 3.

The Federal Circuit has recently provided guidance as to the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir, 2005). First, the Court indicated that the specification disclose "that an invention is useful to the public as disclosed in its current form." *Id.* at 1371. Second, the Court further noted that the specification "also show that that claimed invention can be used to provide a well-defined and particular benefit." *Id.*

The Applicants have provided in the specification that the claimed nucleic acid molecules provide identifiable benefits, for example, encoding triose phosphate isomerase, vacuolar H^+ translocating-pyrophosphatase, sucrose synthase, hexokinase, fructose 1,6-bisphosphate aldolase, fructose 6-phosphate 2-kinase, invertase, fructokinase, NDP-kinase, or UDP-glucose pyrophosphorylase (*see, e.g.*, specification at page 24, lines 7-14 and page 244, Table A); as nucleic acid molecule markers and probes for each of these encoding sequences (*see, e.g.,* specification at page 71, line 8 through page 75, line 2); to identify and obtain nucleic acid homologues of these coding sequences (*see, e.g.,* specification at page 83, line 5 through page 84, line 15); in microarrays as gene-specific targets (*see, e.g.,* specification at page 104, line 3 through page 106, line 9); to identify the presence or absence of a polymorphism (*see, e.g.,* specification at page 85, line 20 through page 93, line 13); to determine the level or pattern of expression of proteins or mRNAs associated with one of these coding sequences (*see, e.g.,* specification at page 99, line 3 through page 103, line 18); and to overexpress or suppress one or

more of these coding sequences in a transgenic plant (*see, e.g.,* specification at page 129, line 9 through page 132, line 3). Any of these utilities described alone is enough to satisfy Section 101.

The Examiner appears to challenge the credibility of the presently asserted utilities. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [she] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in the original); M.P.E.P. § 2107 ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided ..."). Here, the Examiner has not even attempted to meet this burden.

Instead, the Examiner merely asserts that "sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities." Office Action at page 4. The Examiner lists several scientific publications that apparently describe the difficulty in predicting protein function from other sequences. *Id.* at page 5.

First, an Examiner must accept a utility by an Applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See, In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992), emphasis added. "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such as assertion." Federal Register 66(4):1096, Utility Guidelines (2001), emphasis added. The Examiner has neither provided sufficient evidence nor sound scientific reasoning. What the Examiner has provided are a few scientific publications indicating that sequence and structural homology apparently cannot rigorously be correlated with functionality.

Second, "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added. "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, at page 2100-43. The specification provides such a reasonable correlation through sequence identity. An 80 percent identity to known plant sucrose enzymes is a thoroughly reasonable correlation. *See, e.g.,* specification at page 244, *et seq.* (Table A).

The Applicants have disclosed several specific, substantial and credible utilities for the claimed nucleic acid sequences. The specification also indicates, by way of the description of the enzymatic function of the recited enzymes, that each enzyme has well-known enzymatic

functions in the art. *See, e.g.,* specification at page 5, line 3 through page 14, line 19. Further, the specification has provided a detailed description of the characterization of the enzymes and their role in the plant sucrose pathway. *See, e.g., Id.* Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Moreover, these utilities are specific to the claimed nucleic acid sequences, not, as the Examiner denigrates "generally applicable to any nucleic acid." Office Action at page 3.

The Examiner also denigrates the Applicants' argument that the claimed nucleic acid molecules can be used as probes or as a source for primers for the specified coding sequences. The Examiner does not find this use persuasive because "while ... the claimed nucleic acid molecules '*may be employed* to obtain other nucleic acid molecules' (emphasis added), the specification does not indicate that any such nucleic acid molecules *had been* obtained ...". *Id.* at page 6. The Examiner is respectfully reminded that any challenge to an Applicant's assertion of utility must be supported by sound scientific reasoning or sufficient evidence. The Examiner has provided neither and therefore retains the initial burden of challenging the presumptively correct assertion of utility. *Brana*, 51 F.3d at 1567, 34 U.S.P.Q.2d at 1441. The Examiner cannot shift this burden to the Applicants.

In conclusion, because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so with sufficient specificity and reasonable correlation in the present application, the rejection under 35 U.S.C. § 101 is incorrect and the Applicants respectfully request its withdrawal.

2. Claim Rejections under 35 U.S.C. § 112, first paragraph (Enablement):

Claims 2 and 7 to 27 were rejected under 35 U.S.C. § 112, first paragraph, for "failing to comply with the enablement requirement." Office Action at page 7. The Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101. Consequently, the rejection under 35 U.S.C. § 112, first paragraph (enablement), is improper and the Applicants respectfully request reconsideration and withdrawal of this rejection.

3. Claim Rejections under 35 U.S.C. § 112, first paragraph (Written Description):

Claims 2 and 18 to 27 were rejected under 35 U.S.C. § 112, first paragraph, for "failing to comply with the written description requirement." *Id.* The Examiner states that the specification fails to provide written description for specific features commonly possessed by members of the genus of claimed nucleotide sequences because "[t]he specification fails to describe any sequences which in fact encode the proteins recited in the instant claims." *Id.* at page 8. The Applicants respectfully traverse this rejection.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A

person of ordinary skill in the art would, after reading the present specification, understand that the Applicants had possession of the claimed nucleic acid molecules (nucleic acid sequences of SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753). The Applicants have provided the nucleotide sequences required by the claims. Accordingly, the Applicants have demonstrated possession of the claimed invention.

The fact that the claims at issue can cover molecules that encode the recited enzymes, the recited sequence joined with additional sequences, or complements of the recited sequence, does not mean that the Applicants were any less in possession of the claimed nucleic acid molecules.[1] It is well-established law that use of the transitional term "comprising" properly leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. Furthermore, it is well established that claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-*

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[1] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

Purina Co. v. Far-mor-Co, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). The Examiner states that "the specification fails to provide written description for 'specific structural features commonly possessed by members of the genus' of the disclosed SEQ ID NOs." Office Action at page 8. The Applicants respectfully disagree and reiterate that the specification as filed satisfies the Federal Circuit's test for written description.

In particular, the Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 11. For example, if a particular nucleic acid molecule contains the nucleotide sequence of SEQ ID NO: 11, then it is a member of the claimed genus of nucleic acid molecules. Conversely, if it does not contains the nucleotide sequence of, for example, SEQ ID NO: 11, then it is a member of the claimed genus of nucleic acid molecules. The same argument applies with equal force to every genus of the claimed nucleic acid molecules. Moreover, closely related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

Notwithstanding the fact that the Applicants have provided an 80 percent identity to known plant sucrose pathway enzymes, *see, e.g.*, specification at page 244, *et seq.* (Table A), and

that the specification also discloses that SEQ ID NO: 935 encodes a sucrose synthase, *see, e.g.*, specification at page 35, line 16 through page 36, line 2, and Table A, in particular at page 255, *et seq.* under the heading "MAIZE SUCROSE SYNTHASE", the Examiner appears to be challenging the credibility of the written description. Once again, the Applicants respectfully remind the Examiner that she must provide sound scientific reasoning or sufficient evidence to support any challenge. In the absence of sound scientific reasoning or sufficient evidence, the Applicants respectfully submit that the rejection under 35 U.S.C. § 112, first paragraph (written description), is improper and respectfully request reconsideration and withdrawal of this rejection.

4. Claim Rejections under 35 U.S.C. § 102:

Claims 2 and 18 to 27 were rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Genebank Accession Numbers J04121, AF022733, U28214, U64818, U72142, and E10417. Claims 2 and 18 to 27 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Genebank Accession Numbers S46215, X02400, M97476, S42124, X85327, U10282, and Z18924. Office Action at pages 8-11. The Examiner states that these Genebank nucleotides teach fragments of SEQ ID NOs: 11, 446, 935, 1108, 2042, 2166, 2252, 2644, 2681, and 2753. *Id.* (emphasis added).

The Applicants respectfully disagree but to facilitate prosecution, claims 2 and 18 to 27 are amended to no longer recite fragments of the claimed SEQ ID NOs. Therefore, the Applicants respectfully request reconsideration and withdrawal of these rejections.

III. CONCLUSION

In view of the foregoing amendments and remarks, the Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5746 if any additional information is necessary for allowance.

Respectfully submitted,

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